Clerk, U.S. District Court
Southern District of Texas
FILED

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David J. Bradley, Clerk of Court

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF TEXAS

CORPUS CHRISTI DIVISION

UNITED STATES OF AMERICA §
v. §
§ CRIMINAL NUMBER
SOUTH TEXAS COMPREHENSIVE §
CANCER CENTERS, PLLC §

C-15-273

CRIMINAL INFORMATION

THE UNITED STATES ATTORNEY CHARGES THAT:

A. Introduction

At all times material to this Information:

1. South Texas Comprehensive Cancer Centers, PLLC, ("STCCC"), was a professional association with clinics located in and around Corpus Christi, Texas, that provided care and treatment for patients with cancer and blood diseases.

2. Montana Health Care Solutions ("MHCS") was a business in Belgrade, Montana, offering prescription drugs for sale to physicians and other health care providers in the United States that had been obtained from foreign sources and that the U.S. Food and Drug Administration ("FDA") had not approved for distribution in the United States.

3. The FDA was the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et. seq.* ("FDCA"). FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce, including the wholesale distribution of prescription drugs. To meet those responsibilities, the FDA enforced the FDCA, which required, among other things, that drugs bear labels and labeling sufficient to allow health care providers and consumers to use them in a safe manner for their intended uses and that the drugs are listed by and manufactured in facilities registered with the Secretary of the United States Department of Health and Human Services. *See* 21 U.S.C. §§ 352(f)(l), 352(o), 353(b)(4)(A), and 360(c).

4. The FDCA defined a "drug" as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; an article (other than food) intended to affect the structure or any function of the body of man or other animals; and an article intended for use as a component of any such article. *See* 21 U.S.C. § 321(g)(1)(B), (C), and (D).

5. A "prescription drug" under the FDCA was a drug that: (i) because of its toxicity and other potential for harmful effects, or the method of its use, or the collateral measures necessary to its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (ii) was limited by an application approved by FDA, to use under the professional supervision of a practitioner licensed by law to administer the drugs. *See* 21 U.S.C.§ 353(b)(l).

6. A drug was "misbranded" under the FDCA unless its labeling bore adequate directions for use. *See* 21 U.S.C. § 352(f)(1). "Adequate directions for use" meant directions under which a layman could use a drug safely and for the purposes for which it is intended. *See* 21 C.F.R. § 201.5. A drug was also "misbranded" if the label failed to bear the symbol "Rx only." *See* 21 U.S.C. § 353(b)(4)(A); *see also* 21 C.F.R. § 201.100(b)(l).

7. The FDCA prohibited introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce a drug that was misbranded. *See* 21 U.S.C. § 331(a).

8. Between February 22, 2010, and January 17, 2012, STCCC purchased from MHCS and caused to be introduced into interstate commerce misbranded prescription drugs, including but not limited to: Aclasta, Almita, Aloxi, Altuzan, Avastin, Dacogen, Eloxatin, Erbitux, Faslodex, Gemzar, Herceptin, Hycamtin, Mabthera, Neulastim, Reclast, Ribomustin, Rituxan, Taxotere, Treanda, Velcade, Venofer, Vidaza, and Zometa.

9. The labeling for the prescription drugs STCCC purchased from MHCS between February 22, 2010, and January 17, 2012, differed from the versions of the drugs the FDA approved for sale in the United States. Among other things, the labeling of the prescription drugs purchased from MHCS failed to bear adequate directions for use and did not include the symbol "Rx only". *See* 21 U.S.C. §§ 352(f)(l) and 353(b)(4)(A); 21 C.F.R. § 201.100(b)(l).

B. The Unlawful Conduct

COUNT ONE

10. Beginning on or about February 22, 2010, and continuing through on or about January 17, 2012, in the Southern District of Texas and elsewhere, Defendant SOUTH TEXAS COMPREHENSIVE CANCER CENTERS, PLLC, caused the introduction and delivery for introduction into interstate commerce of prescription drugs that were misbranded within the meaning of 21 U.S.C. § 352(f)(l) in that their labeling failed to bear adequate directions for use and within the meaning of 21 U.S.C. § 353(b)(4)(A) in that their labels failed to bear the symbol "Rx only".

All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1) and Title 18, United States Code, Section 2.

NOTICE OF INTENT TO SEEK CRIMINAL FORFEITURE

(21 U.S.C. § 334 & § 853(p) and 28 U.S.C. § 2461(c))

11. Pursuant to Title 21, United States Code, § 334 and Title 28, United States Code, § 2461(c), the United States gives notice to Defendant SOUTH TEXAS COMPREHENSIVE CANCER CENTERS, PLLC, that upon conviction for the offenses charged in Count One of the Information, the following property is subject to forfeiture:

> All drugs obtained from or through MHCS between February 22, 2010, and January 17, 2012, that were misbranded when introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce, or which may

not, under the provisions of Title 21 U.S.C. § 331, be introduced into interstate commerce, with an estimated value of at least $900,000.

MONEY JUDGMENT

12. Defendant is notified that upon conviction, a money judgment for $900,000 may be imposed as the value of the property subject to forfeiture, and that the United States may seek the forfeiture of substitute assets.

SUBSTITUTE ASSETS

13. Pursuant to 21 U.S.C. § 853(p), as incorporated by 28 U.S.C. § 2461(c), the Court shall order the forfeiture of any other property of the defendant, up to the value of the property subject to forfeiture, if as a result of any act or omission of the defendant, such forfeitable property or any portion thereof:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third person;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be subdivided without difficulty.

Respectfully submitted,

KENNETH MAGIDSON
UNITED STATES ATTORNEY

By: ______________________
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